

Appl. No.: 10/030,933
Amendment dated June 27, 2005
Reply to Office action of January 26, 2005

REMARKS/ARGUMENTS

Claims 38-60 are currently pending in the present application. Previously pending claims 19-37 have been canceled by the foregoing amendment.

Amendments to the Claims - New Claims

Canceled independent process claims 19 and 30 have been rewritten as new independent claims 38 and 49, respectively, in part to direct step (b) to the basis of the invention, that is, the adjustment up or down of the pH to form the crosslinker-free biopolymer composition. New independent process claim 53 is also added by the amendment.

New independent claim 38 is now directed to a process for preparing a three-dimensional crosslinker-free composition, which was the product also obtained in canceled independent claims 19 and 30. New independent claim 38 adds the pH value of the aqueous mixture of step (a) and refers to adjusting the pH up or down to a value of about 4.0 to 8.5 to form a crosslinker-free composition comprised of physically interlinked fibers. The underlined portion has also been added. Referring to the subject specification, support for adjusting the pH up or down is found on page 4, lines 21-30, and on page 7, lines 13-37. (The latter includes support for dependent claims 43-45.) Support for adjusting the pH up or down to the value of about 4.0 to 8.5 is found on page 8, lines 17-21. Support for a starting pH of the aqueous mixture of step(a) of 1 to 12 of claim 38 and preferred starting pH of 4 to 10 per new dependent claim 41 is found on page 10, lines 5-6. Support for "comprised of physically interlinked fibers" is found on page 4, lines 21-through page 5, line 15.

Support for the additional step of dependent claim 46 of, "after the adjusting the pH in step (b), allowing the crosslinker-free biopolymer composition to stand, without mixing, for 10 minutes to 10 hours", is found on page 11, lines 3-7.

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In step(a) of new independent claim 49, the aqueous mixture may also optionally contain "5 to 10% by weight of additives selected from the group consisting of polyols, lignin, polyose, pectin, cellulose and synthetic polyester and polyamide fibers". Step (b), adjusting the pH up or down then proceeds without adding any further additives. The resulting aqueous mixture of step(a) has a viscosity of from 10,000 mPas to 40,000 mPas and a pH value of from 1 to 12. Support for the list of optional additives is found on page 10, lines 18-34. Support for adding optional additives at this step and the viscosity adjustment to 10,000 mPas to 40,000 mPas is found on page 11, lines 24-34.

By the foregoing new claims, a third independent claim, claim 53, is added. The primary difference between new claim 53 and new claim 38 is the insertion of another step after the pH adjusting step(c). The inserted step(c) is directed to allowing the crosslinker-free biopolymer composition to stand, without mixing, for 10 minutes to 10 hours. Support for this inserted step is found on page 11, lines 3-7 (as noted above regarding new claim 46).

Applicants submit that no new matter has been introduced by the foregoing amendments. The appropriate fee for the three additional total claims is included on the fee sheet submitted herewith. A complete listing of all claims ever presented is included herein in accordance with 37 C.F.R. §1.121(c). Entry of the amendments is therefore deemed proper and respectfully requested.

Traversal of Rejection for Obviousness

In the subject Office Action (the first office action pursuant to Applicants' Request for Continuing Examination), the Examiner again maintains the rejection claims 19-37 under 35 U.S.C. §103(a), as being unpatentable over U.S. Pat. No. 5,990,381 of Nishihara (hereinafter referred to as "Nishihara"). In making this rejection in the Final Action dated June 16, 2004, the Examiner stated:

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"Specifically, the artificial cartilage disclosed in Nishihara may be prepared by using additional components, such as hyaluronic acid, known in the art as a polysaccharide (See Column 6, lines 14-41: and Example 8). This disclosure, in the view of the examiner, reads on the applicant's claim limitation of an "aqueous mixture of a polysaccharide biopolymer". Here, the examiner interprets the word "mixture" in an open, broad sense such that it may contain components that are not polysaccharide biopolymers."

(emphasis added)

Applicants submit, to the contrary, that the presently claimed processes according to new independent claims 38, 49 and 53 are neither disclosed nor suggested by Nishihara. Neither the processes of Nishihara or the resulting product of Nishihara disclose or suggest (1) a starting mixture consisting essentially of a polysaccharide biopolymer, nor one having a particular viscosity, (2) adjusting the pH up or down to form a crosslinker-free biopolymer composition or any composition comprised of physically interlinked fibers, nor (3) the formation of a three dimensional product as a result of the dewatering step. Nor, does Nishihara disclose or suggest the adjustment of the pH up or down to a particular level, such as to about 4.0 to 8.5, to obtain a composition for dewatering.

The end point of the Nishihara dewatering step is a level of moisture suitable for the ensuing sintering step - which is needed to produce the Nishihara artificial cartilage end product.

In the rejection, the examiner refers to the following statement (and to example 8) in Nishihara, at col. 6, lines 16-18, to show that its artificial cartilage compositions may contain hyaluronic acid, which the examiner states is known in the art as a polysaccharide:

"The artificial cartilage of the invention preferably comprises one or more components selected from hyaluronic acid, chondroitin sulfate, various nucleic acids and various amino acids, in addition to the collagen and hydroxyapatite described above."

(emphasis added)

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Nishihara describes its invention, at col. 5, lines 51-57, as follows:

"The biomedical materials of the invention comprise hydroxyapatite and a collagen derived from Chondrichthyes having no antigenicity. In order to confer strength on an artificial bone, hydroxyapatite and collagen need to be sintered. However, since collagen does not remain under standard sintering conditions (around 1000.degree. C.), it is necessary to sinter them at a low temperature as described later."

(emphasis added)

"Hydroxyapatite" is described in Nishihara, at col. 5, lines 24-26, as follows:

"Hydroxyapatite expressed by the formula $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ is one of the representative calcium phosphate ceramics and is the major constituent mineral in bone and teeth."

From these quotes it can be seen that the artificial cartilage material of Nishihara et al. always contains both collagen (actually, specifically shark-derived collagen) and hydroxyapatite and that the solid form cartilage material is not formed until after the dewatering step - with a sintering step.

See also Example 8, which describes the making of an artificial cartilage composition including hyaluronic acid, but also including collagen and hydroxyapatite, wherein, as described in the foregoing quotes, the resulting partially dewatered product is subjected to sintering to form the artificial cartilage.

Thus, Nishihara does not disclose or suggest adjusting the pH of a composition containing hyaluronic acid in order to form a crosslinker-free biopolymer composition comprised of physically interlinked fibers. Nor, does Nishihara disclose or suggest the formation of a three-

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dimensional structure upon dewatering. No three dimensional structure is formed in the Nishihara process until the sintering process which follows the dewatering step.

With regard to new independent 53, Nishihara neither disclose nor suggests allowing the aqueous mixture to stand without stirring prior to dewatering. See, for example, Example 8.

For the foregoing reasons, Applicants respectfully submit that Nishihara, taken as a whole, fails to establish a *prima facie* case of obviousness with respect to new claims 38-60. Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. §103(a) based upon Nishihara and issuance of a Notice of Allowance for all pending claims are respectfully requested.

Respectfully submitted,

ANDREA HEILEMANN, *et al.*

6/27/05
(Date):

COGNIS CORPORATION
300 Brookside Avenue
Ambler, PA 19002

By: Arthur G. Seifert
ARTHUR G. SEIFERT
Registration No. 28,040
Telephone: (215) 628-1129
Facsimile: (215) 628-1346

AGS:mc

Enclosures: 1. Request for Extension of Time
2. Fee Transmittal